

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY  
PATENT LITIGATION

)  
)  
)  
)

~~MDL NO. 1592~~

03-11329-MLW

ORDER

WOLF, D.J.

June 14, 2004

In light of the Trustees of Columbia University in the City of New York's Emergency Motion to Seal Document and Restrict Access to Confidential Information, it appears that one topic that may be discussed at the June 22, 2004 conference is a protective order to protect confidential information that is disclosed during discovery. Therefore, attached for the parties' consideration is a copy of a protective order this court entered in Biogen, Inc. v. Berlex Laboratories, Inc., on March 3, 1997.

  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

\_\_\_\_\_  
BIOGEN, INC.,

Plaintiff,

v.

\_\_\_\_\_  
BERLEX LABORATORIES, INC.,

Defendant.

CIVIL ACTION NO. 96-10916-MLW

\_\_\_\_\_  
BERLEX LABORATORIES, INC.,

Plaintiff,

v.

\_\_\_\_\_  
BIOGEN, INC.,

Defendant.

CIVIL ACTION NO. 96-12487-MLW

~~PROPOSED~~ <sup>11/15/03</sup> ORDER REGARDING  
CONFIDENTIALITY OF DISCOVERY MATERIALS

WHEREAS, in accordance with Fed. R. Civ. P., Rule 26(c), to protect the legitimate interests of the parties in maintaining the confidentiality of certain sensitive or proprietary information.

IT IS HEREBY ORDERED:

1. Scope

This order shall be applicable to and govern all documents, things and information produced or furnished during the course of this action, including initial disclosures, depositions, documents produced in response to requests for production of documents, answers to interrogatories, responses to requests for admissions and all

other discovery, as well as pleadings, briefs, memoranda, or other materials furnished by or on behalf of any party to this action or nonparty.

2. Definitions

(a) "Discovery materials" means anything produced as initial disclosures or in response to discovery requests, including, but not limited to, documents, things, deposition testimony, answers to interrogatories and requests for admissions.

(b) "Producing Party" or "Designating Party" means a party to this action or any nonparty, on behalf of which documents, things or information are furnished or produced, during the course of this litigation, in response to requests for production of documents, interrogatories, requests for admissions, depositions, or any other request for discovery pursuant to the Federal Rules of Civil Procedure, or in the form of pleadings, briefs, memoranda, or other form of information produced or furnished by or on behalf of such a party or nonparty.

(c) "Independent Outside Expert" means (i) an expert or consultant retained for the purpose of this litigation, not a current employee of a party or of a person or entity affiliated with a party, and (ii) who agrees for a period of two years following the conclusion of the trial in this action to provide at least ten days written notice to outside counsel for the parties of any intent to provide consulting or other services relating to regulatory approval, including U.S. Food and Drug Administration approval, or the development of a manufacturing process or manufacturing line for beta-interferon to the following entities and their affiliates: Schering AG; Berlex Laboratories, Inc.; Stanford University; Rentschler Arzneimittel GmbH & Co.; Dr. Rentschler Biotechnologie GmbH & Co.; Biogen, Inc.; and Ares-Serono, Inc. If the contemplated consulting or other services are to be provided to a

party, that party shall likewise have the obligation to provide at least ten days written notice to the other party. If the other party files with this Court a written objection to the contemplated consulting or other services within ten days, the other party and the expert shall, in good faith, attempt to resolve any such objections. This Court shall retain jurisdiction over this matter for purposes of resolving any remaining objections. The contemplated consulting or other services shall not be commenced until all objections have been resolved. An "Independent Outside Expert" may be an employee of an entity or person itself qualifying as an "Independent Outside Expert" under this paragraph.

(d) "Confidential Information" shall mean confidential proprietary technical, scientific or business discovery materials which the producing party, in good faith, believes comprise "trade secret or other confidential research, development, or commercial information" within the meaning of Rule 26(c)(7), Fed. R. Civ. P., that is designated as such by the producing party pursuant to Section 3 hereof.

(e) "Confidential Restricted" shall mean Confidential Information which is commercial, pricing, costing, or marketing information relating to the producing party or the producing party's commercial products or planned commercial products, and which is designated as such by the producing party pursuant to Section 3 hereof.

(f) "Confidential/Copying Restricted" shall mean confidential discovery materials which:

- (i) are part of, or refer to, clinical studies or information including, but not limited to clinical studies contained in the

Product License Applications ("PLA") relating to AVONEX™ or Betaseron®; or

(ii) are part of, or refer to, product manufacturing or characterization methods, processes, designs, or plans, including, but not limited to, the Establishment License Applications ("ELA") relating to AVONEX™ or Betaseron®,

and which are designated as such by the producing party pursuant to Section 3 hereof.

3. Designation of Confidential Information

(a) Documents, things, and portions thereof, shall be designated as confidential by stamping or otherwise marking them with the words "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" as the case may be. In the case of multi-page documents, each page which is designated as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" shall be appropriately stamped.

(b) Any party or nonparty may designate the deposition testimony of any witness or any portion thereof (including any exhibit) as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" by advising the reporter and all parties of such fact on the record during the deposition or in writing at any time within fourteen days after actual receipt of the transcript by counsel for the designating party. The reporter shall also be advised to limit distribution of the transcripts to outside counsel for the parties and the deponent (or his or her attorney).

4. Initial Inspection of Documents and Things

Designation of produced documents and things as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" may be made by the producing party after an initial inspection and before copying. If the producing party elects not to make such designation before an initial inspection, all documents produced for inspection and the information contained therein shall be treated as "Confidential" until copies are provided to the receiving party, unless they are designated "Confidential Restricted," or "Confidential/Copying Restricted" at or before the initial inspection.

5. Use of Discovery Materials Designated as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted". Discovery materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" and the information contained therein, shall be used only in connection with the conduct of this action (including use in briefs, memoranda, correspondence and other documents relating thereto) and shall not be used for any other purpose except upon written consent of the designating party or upon order of the Court. This Stipulation and Order has no effect upon, and shall not apply to (a) any producing party's use of its own "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" materials for any purpose or (b) any person's use of documents or other information developed or obtained independently of discovery in this action for any purpose.

Furthermore, nothing in this Stipulation and Order shall bar or otherwise restrict any attorney from rendering advice to a party-client in this action and, in the course thereof, relying upon such attorney's knowledge of "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" information; provided, however, that in rendering such advice and in otherwise communicating with such

client, the attorney shall not disclose any "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" information to persons not authorized under this Stipulation and Order without obtaining prior written approval from the Producing Party.

6. Restrictions on the Disclosure of Discovery Materials Designated

"Confidential." Discovery materials designated "Confidential," and the information contained therein, shall not be disclosed to any person except:

(a) Outside counsel for the non-designating party (including law firm personnel and document processing vendors assisting them in this litigation, provided that, if any such personnel or vendors are not employees of the outside counsel, they first execute the Agreement to Maintain Confidentiality, attached as Exhibit A);

(b) Alphonse R. Noë for Biogen and Deborah D. Tanner for Berlex;

(c) Two in-house experts of the non-designating party who are actively engaged in using his or her knowledge and expertise to assist legal counsel, but only as reasonably necessary in support of this litigation;

(d) Independent Outside Experts retained by the non-designating party;

(e) Any person who is or may be a witness in this action, and counsel for such person, to the extent authorized by paragraph 8 below;

(f) Court personnel and court reporters; or

(g) Other persons only upon consent of the producing party or upon order of the Court. Administrative/clerical staff of individuals identified in categories (b)-(g) above may have access to "Confidential" information to the extent reasonably necessary for such individuals to accomplish their roles.

7. Restrictions on the Disclosure of Discovery Materials Designated as "Confidential Restricted" And "Confidential/Copying Restricted."

(a) Discovery materials designated "Confidential Restricted," and the information contained therein, shall not be disclosed to or discussed with any person except those described in paragraphs 6(a) , (b), and (d)-(g).

(b) Discovery materials designated as "Confidential/Copying Restricted," and the information contained therein, shall not be disclosed to or discussed with any person except those described in paragraphs 6(a), (b), and (d)-(g) hereof. Further, such discovery materials shall be reviewed by persons described in paragraphs 6(b) and 6(d) only:

- (i) at the offices of outside counsel for one of the parties; or
- (ii) alternatively, upon the request of a non-designating party, the designating party shall make a copy of the portion of "Confidential/Copying Restricted" information requested by the particular Independent Outside Expert available for inspection at a secure location in the city where the particular Independent Outside Expert resides or works.

(c) "Confidential/Copying Restricted" information may be photocopied only by the designating party and outside counsel for the parties and shall not be photocopied or removed from the premises at which it is inspected by or for any Independent Outside Expert without approval from the producing party or a supplemental order from this Court.



8. Disclosure to Witnesses.

(a) Any person currently employed by a party or retained as an expert witness by a party may be examined at trial or upon deposition concerning any discovery materials designated by such party as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted."

(b) Documents designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" may be disclosed without prior notice to the producing party to a person other than those identified in paragraph 8(a) who is or may be a witness only if the document indicates on its face that the person was an author, addressee or recipient of the document, or the document came from such person's files.

(c) Before a party may examine as a witness at trial or upon deposition any person other than those identified in paragraphs 8(a) or (b) concerning discovery materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted," the examining party shall, at least one week prior to such examination, notify the producing party, in writing, of its intent to examine such person concerning such materials. A producing party receiving a notification of intent to examine concerning "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" material may object to the proposed examination by giving written notice of such objection to the party seeking to conduct the examination. Such notice shall be delivered within three calendar days of receipt of the notification of intent to examine to which objection is made. If an objection is made, the proposed examination shall not take place until the objection is resolved by agreement of the parties or determined by the Court. Failure to object within the time period set forth above shall be deemed a consent. If the objection cannot be

resolved by agreement of the parties, the party making the objection shall have the burden of persuading the Court that the intended disclosure should not occur.

9. Certification of Persons to Whom Discovery Materials are Disclosed. Prior to disclosure of any discovery materials designated "Confidential" to any person described in paragraphs 6(b)-(d), disclosure of discovery materials designated "Confidential Restricted" or "Confidential/Copying Restricted" to any person described in paragraphs 6(b) and 6(d) and disclosure of discovery materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" to any nonparty witness pursuant to paragraph 8, each such person shall read a copy of this Stipulation and Order and read and sign a certificate in the form of Exhibit A attached hereto (conformed to refer to the category or categories of discovery materials to which such person is permitted access).

Further, no fewer than ten (10) calendar days in advance of the initial disclosure of confidential discovery materials to any in-house expert pursuant to paragraph 6(c) (materials designated "Confidential") or to any independent outside expert pursuant to paragraphs 6(d) and 7 (materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted") the party proposing to disclose such materials shall submit in writing to counsel for the other parties in following:

- (i) the name, address, and job title of such person;
- (ii) the name and address of his or her employer;
- (iii) the employment history of the expert (in the case of independent outside experts); and
- (iv) a certificate in the form of Exhibit A, attached hereto, signed by the expert.

If the opposing party objects to the disclosure of the information to such expert, it shall notify the proposing party in writing, within seven (7) calendar days of receipt, of its objection and the grounds therefor. If no such objection is made, the proposing party may disclose the information subject to the terms hereof. If, however, the opposing party timely objects to the disclosure and such dispute is not resolved on an informal basis between the proposing party and opposing party as specified herein, the proposing party shall submit such objection to the Court for ruling. In the event of such written objection, the disclosure of discovery materials designated as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" to such an expert shall be withheld pending the ruling of the Court or written agreement between the parties.

10. Resolution of Challenges to Designations. The parties to this action are not obliged to challenge the designation of any discovery materials as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" at the time of receipt, disclosure, or designation thereof, and a failure to do so shall not preclude a subsequent challenge to the classification of the material. In the event that a receiving party seeks to challenge the appropriateness of any such designation, such party shall consult in good faith with the designating party in an effort to resolve the matter on an informal basis. In the event no agreement is reached, the burden shall be upon the receiving party to seek an order permitting disclosure of the disputed materials. The receiving party shall give no less than five calendar days written notice to the producing party before seeking such an order, identifying (with as much specificity as is practicable) the document or testimony that counsel contends is not entitled to protection. Any document or testimony incorporating confidential material as to which such application to the Court is made shall continue to be

treated as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted," as the case may be, until the Court rules or the motion is otherwise resolved. The producing party shall have the burden of persuading the Court that good cause exists for the designation of materials as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted."

11. Inadvertent or Unintentional Production.

(a) The inadvertent or unintentional production of discovery materials without a confidentiality designation shall not be deemed a waiver in whole or in part of a party's claim of confidential treatment under the terms of this Stipulation and Order. Any document that initially is produced without bearing a confidentiality designation may later be so designated, with respect to future disclosure by the producing party, and the receiving party shall make all reasonable efforts to retrieve all copies, if any, of such document disclosed to persons other than those authorized in Sections 6 and 7 hereof and to prevent further use or disclosure of confidential information contained therein by such persons.

(b) If information subject to a claim of attorney-client privilege, attorney work product or any other legal privilege protecting information from discovery is inadvertently produced to a party or parties, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product or other ground for withholding production to which the producing party or other person otherwise would be entitled. If a claim of inadvertent production is made pursuant to this Paragraph, with respect to information then in the custody of another party, such party promptly shall return to the claiming party or person that material and all copies or reproductions thereof as to which the claim of inadvertent production has been made, shall destroy all notes

or other work product reflecting the contents of such material, and shall delete such material from any litigation-support or other database. The party returning such material may then move the Court for an order compelling production of the material, but such motion shall not rely upon in any manner or assert as a ground for entering such an order the fact or circumstances of the inadvertent production.

12. Protection of Nonparty Discovery Materials. In the event that any nonparty shall be called upon, by subpoena or otherwise, to provide or produce discovery materials considered confidential or subject to a confidentiality requirement by such nonparty, such nonparty shall become covered by the terms of this Stipulation and Order by notifying outside counsel for all parties in writing. Upon service of such notice, such nonparty may designate discovery materials as "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" in the manner set forth in this Stipulation and Order, and such nonparty's "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" information shall be treated in the same manner and subject to the same terms as the "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" information of a party to this action.

13. Filing of "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted" Materials.

(a) The filing with the Court of any discovery materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted," or of briefs or other papers containing or referencing such materials, shall be made in conformance with the procedures set forth in Rule 7.2 of the Local Rules of this Court. The Clerk of this Court is to maintain such information under seal unless the Court denies the Motion To Impound, in which case the Clerk will permit a party to retrieve the information prior to it being placed in the public file.

(b) Any discovery materials designated "Confidential," "Confidential Restricted," or "Confidential/Copying Restricted," or briefs or other papers containing or referencing such materials that are filed with the Court shall be filed in a sealed envelope or box. Marked on the outside of the sealed envelope or box shall be the title of the action, an identification of the document or thing within, and a statement in substantially the following form:

CONFIDENTIAL [RESTRICTED][COPYING RESTRICTED]

FILED UNDER SEAL PURSUANT TO THE PROTECTIVE ORDER OF [DATE] GOVERNING CONFIDENTIALITY OF DOCUMENTS AND INFORMATION OBTAINED DURING THE COURSE OF THIS LITIGATION. THIS ENVELOPE IS NOT TO BE OPENED NOR THE CONTENTS THEREOF DISPLAYED OR REVEALED EXCEPT BY COURT ORDER.

(c) All such materials filed under seal shall be maintained by the clerk in a secure area to be designated by the Court. If the impoundment order for any such materials provides a cut-off date, the materials shall be returned to outside counsel for the party who filed it at the cut-off date.

(d) If a party files a document under seal, a second "nonconfidential" version shall also be filed with the Court. Each page from which material subject to this Stipulation and Order has been deleted shall bear a legend so indicating.

14. Maintenance of "Confidential," "Confidential Restricted" or "Confidential/Copying Restricted" Materials by the Parties. All materials designated "Confidential," "Confidential Restricted" or "Confidential/Copying Restricted" shall be maintained at all times with reasonable precautions taken to ensure that access to such materials is restricted to persons entitled to have such access pursuant to this Stipulation and Order.

15. Use of "Confidential," "Confidential Restricted" or "Confidential/Copy Restricted" Materials at Trial. This Stipulation and Order is limited to the pretrial phase of the litigation and issues relating to confidentiality and public access to information presented at trial will be addressed separately, if necessary.

16. Return or Destruction of Confidential Materials Upon Termination of This Action. At the final conclusion of this action (including any appeals) and unless the Court otherwise orders, any discovery materials designated "Confidential," "Confidential Restricted" or "Confidential/Copying Restricted" and any copies thereof which have been made shall be returned to the producing party or, in the alternative, such materials and any copies thereof shall be certified in writing to have been destroyed, and all work product reflecting an opposing party's confidential information shall be destroyed, except that outside counsel may retain one copy of all papers filed with the Court or offered in evidence, subject to the terms of this Order.

17. Continuing Effectiveness of This Stipulation and Order. This Stipulation and Order shall continue to be binding after the conclusion of this action, except that a receiving party may seek the written permission of the producing party or further order of the Court with respect to dissolution or modification of this Stipulation and Order.

18. Court Approval. The parties agree promptly to submit this Stipulation and Order to the Court for approval, and further agree that, pending approval by the Court, this Stipulation and Order shall be effective as if approved and, specifically,

that any violation of its terms shall be subject to the same sanctions and penalties as if this Stipulation and Order had been entered by the Court.


SO ORDERED:

  
United States District Judge

Dated: March 3, 1997

STIPULATED TO BY:

BIOGEN, INC.

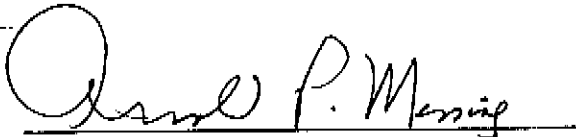
  
William F. Lee (BBO #291960)  
David B. Bassett (BBO #551148)  
Hale and Dorr LLP  
Boston, MA 02109  
(617) 526-6000

Albert E. Fey  
James F. Haley, Jr. (BBO #217220)  
Douglas J. Gilbert  
Gerald J. Flattmann, Jr.  
Fish & Neave  
1251 Avenue of the Americas  
New York, NY 10020  
(212) 598-9000

OF COUNSEL:

Michael J. Astrue (BBO #542546)  
Vice President and General Counsel  
Biogen, Inc.  
Fourteen Cambridge Center  
Cambridge, MA 02142  
(617) 679-2400

BERLEX LABORATORIES, INC.

  
Arnold P. Messing (BBO #343940)  
Choate, Hall & Stewart  
Exchange Place, 53 State Street  
Boston, MA 02109  
(617) 248-5000

Richard W. Clary  
Stephen S. Madsen  
Cravath, Swaine & Moore  
Worldwide Plaza, 825 Eighth Avenue  
New York, NY 10019  
(212) 474-1000

OF COUNSEL:

Anthony J. Zelano  
Millen, White, Zelano & Branigan, P.C.  
Arlington Courthouse Plaza I  
Suite 1400  
2200 Clarendon Boulevard  
Arlington, VA 22201

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party by mail (by hand) on 2/28/97



EXHIBIT A

AGREEMENT TO MAINTAIN CONFIDENTIALITY

I have received and read a copy of the Stipulation and Order Regarding Confidentiality of Discovery Materials in this case and I agree to abide by its terms. I understand that materials disclosed to me and designated "Confidential," "Confidential Restricted" or "Confidential/Copying Restricted" are subject to various restrictions of use and disclosure, including the restriction that they are to be used solely in connection with this litigation, and not for any business or other purpose whatsoever. I further agree to submit to the jurisdiction of the United States District Court for the District of Massachusetts for the purpose of enforcing my compliance with the Stipulation and Order Regarding Confidentiality of Discovery Materials.

DATED this \_\_\_\_ day of \_\_\_\_\_, 1997.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Sworn under the pains and penalties of perjury:

Signature: \_\_\_\_\_